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10/595,431	01/03/2007	Gerhard Tivig	PHDE030358US	9506

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER
BITAR, NANCY

ART UNIT	PAPER NUMBER
2624	

NOTIFICATION DATE	DELIVERY MODE
03/31/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _1/14/2011_.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _3,4,12,14,16-18,20-22 and 24-28_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _3,4,12,14,16-18,20-22 and 24-28_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _19 April 2006_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☒ All   b)☐ Some * c)☐ None of:

      1.☒ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1.   Applicant's response to the last Office Action, filed 9/14/2010, has been entered and made of record.

2.   Claims 3, 4, 12, 14, 16-18, 20-22, 24-28are currently pending.

3.   Applicants arguments filed 01/14/2010 have been fully considered but they are not persuasive.

4.   Applicant argues that none of the display options noted by the examiner teach or fairly suggest displaying a histogram with a cumulative curve superimposed having common axes and common scales. Additionally applicant argues that neither Seely et al nor Zalenski et al nor the combination teaches displaying a cumulative curve superimposed on a histogram as the medical measurement is received.

In response, Seely teaches a method and apparatus (100) for providing continuous analysis and display of the variability of multiple patient parameters monitored by multiple bedside monitors (106a-106c) for each patient (102). Each monitor is connected to a patient interface and to a patient data storage unit (115) and a processor (113). Each monitored patient parameter is measured in real-time (i.e. as the medical measurement is received). Data artifacts are removed, and variability analysis is performed based upon a selected period of observation. Variability analysis yields variability of the patient parameters, which represents a degree to which the patient parameters fluctuate over time, to provide diagnostic information (see abstract). Seely teaches in figures 5 and 6A,6B teaches displaying a histogram and the histogram is updated

(paragraph[0085]). The Log-log Plot 520, 540 is simply a linear representation of the frequency

distribution histogram 518, 538 on a log-log plot of frequency vs. variation. The straight-line

distribution of points is characteristic of 1/f noise. The best fit of a straight line through the data

points may be derived using standard linear regression analysis, and can also help inform the

user respecting the appropriateness of this particular technique. The present invention calculates

the slope of the line 522, 542 of the log-log plot and the x-intercept 524, 544. These values can

be displayed as pairs of dynamic variability parameter histograms 526, 546. The slope is

represented by one histogram 528, 548 and the intercept by another histogram 530, 550.

Examiner refers to the secondary reference Zaleski et al (US 2003/0101076).Zaleski teaches the

cumulative curve being cumulative of the series of histogram wherein the model (expected)

trajectories are compared with the measured (actual) trajectories of the patient. The comparison

is evaluated to determine the degree of "likeness" or "sameness" between the expected and actual

trajectories. Finally, by combining all trajectories together, it is possible to determine a

cumulative estimate of "sameness" using a .chi..sup.2-square test to show that the patient's

cardiovascular parameters are either following or not following an expected path

(paragraph[0058-0059]). Zaleski teaches the use of graphical display that the physician maps

pulls up data and request a plot or any other graph in order to have a real time assessment of the

particular parameters in comparison to the historical record .Therefore the combination of Seely

and Zalenski the cumulative curve been displayed as the medical image are being received. All

remaining arguments are reliant on the aforementioned and addressed arguments and thus are

considered to be wholly addressed herein.

Examiner Notes

5.   Examiner cites particular columns and line numbers in the references as applied to the

claims below for the convenience of the applicant. Although the specified citations are

representative of the teachings in the art and are applied to the specific limitations within the

individual claim, other passages and figures may apply as well. It is respectfully requested that,

in preparing responses, the applicant fully consider the references in entirety as potentially

teaching all or part of the claimed invention, as well as the context of the passage as taught by

the prior art or disclosed by the examiner

Claim Rejections - 35 USC § 103

6.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or
> described as set forth in section 102 of this title, if the differences between the subject
> matter sought to be patented and the prior art are such that the subject matter as a whole
> would have been obvious at the time the invention was made to a person having ordinary
> skill in the art to which said subject matter pertains. Patentability shall not be negatived
> by the manner in which the invention was made.

7.   Claims 3, 4, 12, 14, 16-18, 20-22, 24-28 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Seely et al (US 2003/0117296) in view of Zaleski et al (2003/0101076).

As to claim 20, Seely et al teaches the method of automatically displaying medical

measurement data in which a computer: receives the medical measurement data (107, figure 1)

automatically converts in real time the received measurement data into data for a histogram

including a updated in real time, (paragraph [0075], [0085]), during the conversion, generates a

cumulative curve indication of the medical measurement data the cumulative curve being

cumulative of the series of histogram values (figure 5, and 6) and displays the histogram with the

cumulative curve superimposed, the histogram and the cumulative curve having common axes

and a common scales (paragraph [0088-0089]). While Seely et a meets a number of the

limitations of the claimed invention, as pointed out more fully above, Seely teaches the

variability display (paragraph [0085-0090] but fails to specifically teach the histogram includes

an updates in real time values and generating a cumulative curve indicative of the medical

measurement data the cumulative curve being cumulative of the series of histogram values.

Specifically, Zaleski et al. teaches in FIG. 1, the system is implemented in computer hardware

and software configured to operate on a dedicated software application and Web-enabled

hardware computing system to access raw medical facts about patients extracted from lifetime

clinical records and telemetry from available modalities (such as ventilators, pulse oximeters,

ECG monitors, core temperature probes, etc.); and to convert this raw data into mathematical

models for clinical outcome and real-time patient state prediction. Zelski clearly teaches in figure

9 the model (expected) trajectories are compared with the measured (actual) trajectories of the

patient. The comparison is evaluated to determine the degree of "likeness" or "sameness"

between the expected and actual trajectories. Finally, by combining all trajectories together, it is

possible to determine a cumulative estimate of "sameness" using a .chi..sup.2-square test to show

that the patient's cardiovascular parameters are either following or not following an expected

path (see paragraph [0058-0060]) . It would have been obvious to one of ordinary skill in the art

to generate in real-time the histogram data and the cumulative curve in Seely display in order to

have an efficient system which is capable of acting as the foundation on which to establish

predictive methodologies for clinical application that would provide significant advantages in the

process of defining a truly valuable decision support system for the clinician thus providing a

convenient way to perform complex comparative trend analysis .Therefore, the claimed

invention would have been obvious to one of ordinary skill in the art at the time of the invention

by applicant.

As to claim 3, Seely et al teaches a method as claimed in claim 5, further including: filing

the histogram is filled with measurement data from a time window advancing in real time with

selectable fixed length (see figure 6, note that for each patient parameter v.sub.k, a user, typically

an attending physician, may select the number of data points m.sub.k to collect in order to

perform the variability analysis).

As to claim 4, Seely et al teaches a method as claimed in claim 20, wherein, during the

conversion, the computer generates aids for the retrospective analysis of the histograms in the

form of selectable functions that can be displayed on a viewing screen and outputs them together

with the converted data combined as picture signals (note that the process 110 may be selected

by a user from among a plurality of variability analysis options using a user interface 117, see

paragraph [0061]).

The limitation of claim 12 has been addressed in claim 20 above..

Seely teaches the limitation of claim 14 wherein the retrospective analysis aids include a

deviation readout (The simplest method for computing variability parameters involves the

calculation of mean and standard deviation of the frequency distribution of a selected data set.

This information can be updated continuously and displayed visually as a graph. Statistical

interpretation of the frequency distribution is dependent upon whether the distribution is normal

or lognormal. There are standardized means of evaluating whether a distribution is accurately

represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By

calculating the kurtosis and skew, the user may be directed towards choosing an appropriate

distribution. By evaluating the frequency distribution, the mean and standard deviation would

represent the variability parameters for the particular patient parameter under evaluation,

paragraph [0083]).

As to claim 16, Seely et al teaches the medical monitoring device as claimed in claim 28

further comprising an alarm indicator that is triggered measurement of histogram data is

measured above or below a lower or upper alarm limits, (Alarms can be set so that if a variability

histogram is within the normal range, it is displayed in one color (green, for example). If the

value of the histogram rises above or falls below the normal range, it is displayed in a different

color (red, for example), paragraph [0089]).

As to claim 17, Seely et al teaches the medical monitoring device as claimed in claim 28,

wherein the histogram data is binned into histogram bins, the histogram bin size being definable

by the user (The data is plotted in frequency bins, where each bin represents a proportional

amount of variation, as measured by the squared difference from the mean, paragraph [0085]; see

also Zaleski et al paragraph [0039-0040]).

As to claim 18, Seely et al teaches the medical monitoring device as claimed in claim 28

further comprising display means for displaying real-time signal patterns of the medical

measurement data (real-time display, 502, figure 5; note that Zaleski teaches The ongoing results

of the analysis (e.g. the trend) may then be transmitted by Application Server 104 back to User

Interface 105, such as in the form of a graphical display that is updated in real time; see

paragraph [0050]).

As to claim 21, Seely teaches the retrospective analysis aids include at least one of: a

cumulative curve cursor for determining a percentage of time that histogram values are below a

current cumulative cursor position; range-selection cursors for determining a percentage of time

that histogram values are within limits defined by the range-selection cursors; a

variability/stability readout that provides information about variability of the measurement data;

and a deviation and direction-change readout that shows deviation from a mean histogram value

and a direction of measurement data change (The simplest method for computing variability

parameters involves the calculation of mean and standard deviation of the frequency distribution

of a selected data set. This information can be updated continuously and displayed visually as a

graph. Statistical interpretation of the frequency distribution is dependent upon whether the

distribution is normal or lognormal. There are standardized means of evaluating whether a

distribution is accurately represented by a normal or log-normal curve, which include evaluation

of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards

choosing an appropriate distribution. By evaluating the frequency distribution, the mean and

standard deviation would represent the variability parameters for the particular patient parameter

under evaluation, paragraph [0083]).

The limitation of claims 22 and 28 has been addressed above.

As to claims 24 and 26 and 27, Seely teaches the medical monitoring device as claimed in claim 12, wherein the histogram and the cumulative curve are displayed with common axes and scales (figure 5)

As to claim 25, Seely teaches the medical monitoring device as claimed in claim 28, wherein the histogram data includes a series of medical measurement values and the cumulative curve includes a sum of the medical measurement values (paragraph [0085]).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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